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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,555	07/16/2004	Bo Johan Niklas Niklasson	10400-000111/US	5132

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Capitol City TechLaw, PLLC
PO BOX 1210
VIENNA, VA 22183

EXAMINER	
EISEMAN, ADAM JARED	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,555	NIKLASSON, BO JOHAN NIKLAS	
	Examiner	Art Unit	
	ADAM J. EISEMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the applicant initiated interview held on 5/27/2009.

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action during the interview is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 11 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al (US Patent 5,044,372) in view of Liedtke (US Patent 4,765,986) and Engel (US 4,450,845).

Anhauser discloses an epicutaneous test plaster, comprising: a flexible carrier (12) including an adhesive layer (13) for removably adhesion of the epicutaneous test plaster to a skin portion; a plurality of test chambers (around 14) distributed over the adhesive layer of the carrier; a removable cover layer (16) extending over all the test chambers and the carrier, wherein the test chambers are formed as separate chambers, each test chamber including, a support element (14) secured to the carrier and including a support layer adhered to a moisture barrier layer (column 5, lines 30-33), a frame-shaped plastic layer (15) secured on top of and embracing the support element and defining at least some sidewalls of the test chamber that directly confront each other (see figure 1), and wherein the cover layer is removably secured by way of the adhesive layer of the carrier.

However, Anhauser does not expressly disclose that a first layer of adhesive is on the outwardly directed side of the frame-shaped plastic layer; that the frame-shaped plastic layer is foam; or a second layer of adhesive between the foam plastic layer the support element.

Liedtke teaches a layer of adhesive (11) on the skin contacting side of a frame-shaped foam plastic layer (10) of a medical plaster (column 5, lines 35-61; figures 4 and 5). The adhesive layer is for attaching the plastic layer to a test area (column 5, lines 35-61). The adhesive layer extends all the way around the perimeter of the foam layer and has an opening through which a chamber is exposed (column 5, lines 35-61).

Engel teaches a frame shaped layer (element 22) having an adhesive layer on both the top **and** bottom of the frame shaped layer allowing for adhesion and removal from both the skin (adhesive of skin contacting side) **and** a base (adhesive on the base contacting side) (column 3, line 45 – column 4, line 14).

Regarding claims 1, 11 and 18-20; it would have been obvious to one having ordinary skill in the art at the time of invention to substitute Anhauser's frame-shaped plastic layer test chamber and support element with Liedtke's frame-shaped foam plastic layer having a layer of adhesive on the outwardly directed side of the frame in order provide direct adhesion of the frame to skin to prevent leakage of the testing material from the test site. This is substitution of one known element for another to obtain predictable results. Furthermore, it would have been obvious to one of ordinary skill in the art to modify Lietke's foam plastic frame to include a second adhesive layer

on the base/support contacting side of the foam plastic layer as taught by Engel in order to provide attachment between the frame layer and the support layer.

In regards to claim 19, each support element is secured to the carrier by way of an adhesive layer, whose one side is fixed to the carrier and whose other side is fixed to the support element.

5. Claims 2-4, 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser in view of Liedtke and Engel, as applied to claims 1, 11 and 18-20 above, and further in view of Rudiger et al. (US 4,887,611).

The Anhauser/Liedtke/Engel combination as described above does not expressly disclose that the cover layer is a plastic layer with blister bubbles.

Rudiger teaches an upper plastic cover layer (column 3, lines 44-47) with blister bubbles (20) and a lower cover layer, which enclose test chambers. The blister bubbles have a groove (see above 19 in figure 3) in contact with a rim of the test sites. The cover layer of Rudiger improves handling, storage and transport of the plaster (column 3, lines 39-49).

Regarding claims 2-4, 17 and 21; it would have been obvious to one of ordinary skill in the art at the time of invention to substitute Anhauser/Liedtke/Engel combination's cover layer with an upper cover layer with blister bubbles and a lower cover layer as taught by Rudiger in order to achieve the predictable result of enclosing the plaster for handing, storage, and transport purposes.

Further regarding claim 3, Rudiger discloses that the cover layer has a polypropylene layer but does not expressly disclose that the cover layer has a

polyethylene layer. However, Rudiger states that the cover layer should be coated with an inert material (column 3, lines 45-46). Rudiger further teaches that polypropylene and polyethylene are alternative inert plastics (column 2, lines 44-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the polypropylene on the cover layer with polyethylene because the substitution would have yielded predictable results and because Rudiger teaches that these two materials are alternative inert plastics. Furthermore, Liedtke teaches that the cover layer and base layer are an occlusive plastic foil (column 5, lines 35-57). Thus it would have been obvious to one of ordinary skill in the art to use a plastic foil instead of a metal foil as taught by Rudiger as substitution of one known element with another with predictable results.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et in view of and Engel, as applied to claims 1, 11 and 18-20 above, and further in view of Quisno (US 4,450,844).

Although Anhauser states that various materials can be used (column 3, lines 26-31), including treated papers, the Anhauser/Liedtke/Engel combination does not expressly disclose that the cover layer is a paper liner with a silicone layer that faces the test chambers.

Quisno teaches a paper cover liner with a silicone layer that faces test areas (column 4, lines 33-37).

Regarding claim 5; it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the paper liner taught by Quisno for the

cover layer of the Anhauser/Liedtke/Engel combination in order to yield the predictable result of protecting the adhesive until use.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser in view of Liedtke and Engel, as applied to claims 1, 11 and 18-20 above, and further in view of Hoffmann (US RE37,934).

Although Anhauser discloses a flexible porous surgical tape, the Anhauser/Liedtke/Engel combination does not expressly disclose a methacrylate-based adhesive layer.

Hoffmann teaches a methacrylate-based adhesive layer (column 7, lines 13-26) for fixing a plaster to the skin.

Regarding claim 6; it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the methacrylate-based adhesive as taught by Hoffmann for the adhesive of the Anhauser/Liedtke/Engel to achieve the predictable result of adhering a plaster to skin.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser in view of Liedtke and Engel, as applied to claims 1, 11 and 18-20 above, and further in view of Breneman (US 4,543,964).

The Anhauser/Liedtke/Engel combination as described above teaches using a cotton support element (column 5, line 29), but does not expressly disclose that the support element is cellulose-based.

Breneman teaches that cotton and methyl cellulose are known alternative absorbent materials for use in a test plaster (column 4, lines 15-20).

Regarding claim 7; it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted a cellulose-based material as taught by Breneman for the cotton of the Anhauser/Liedtke/Engel combination to achieve the predictable result of providing an absorbent material to hold a test substance.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser in view of Liedtke and Engel, as applied to claims 1, 11 and 18-20 above, and further in view of van der Bend (NL 8701577).

The Anhauser/Liedtke/Engel combination is described above, however it does not expressly disclose that the frame- shaped foam plastic layer consists of a polyethylene foam.

Van der Bend teaches making a frame-shaped foam plastic layer out of a polyethylene foam (see translation submitted by Applicant).

Regarding calim 8; it would have been obvious to one having ordinary skill in the art at the time of invention to have used a polyethylene foam as taught by van der Bend in the frame-shaped foam plastic layer of the Anhauser/Liedtke/Engel combination as simple substitution of one known element for another to yield predictable results.

10. Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser in view of Liedtke and Engel, as applied to claims 1, 11 and 18-20 above, and further in view of Pluim, Jr. (US 4,472,507).

The Anhauser/Liedtke/Engel combination is described above, however it does not expressly disclose that the support element is secured to the carrier by a flexible

double-adhesive tape or that the frame-shaped foam plastic layer is secured to the support element by a flexible double-adhesive tape.

Pluim teaches the use of a flexible double-adhesive tape for use in adhering layers of a carrier together (column 3, lines 17-21).

Regarding claims 9, 12 and 13; The Anhauser/Liedtke/Engel combination teaches the use of an adhesive on the top and bottom of the foam plastic later to adhere the frame to the skin and to a base/support. It would have been obvious to one of ordinary skill in the art at the time of invention to substitute the first and second adhesive layers of the Anhauser/Liedtke/Engel combination with a flexible double-adhesive tape as taught by Pluim as simple substitution of one know element for another to yield predictable results.

11. Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser in view of Liedtke, Engel and Pluim, Jr., as applied to claims 9, 12 and 13 above, and further in view of Kurokawa et al. (US 4,158,359).

The Anhauser/Liedtke/Engel/Pluim Jr. combination is described above; however it does not expressly disclose using a synthetic rubber-based adhesive on the double-adhesive tape.

Kurokawa teaches that synthetic rubber is a known pressure-sensitive adhesive that has no influence on human skin (column 5, lines 33-38).

Regarding claims 10 and 14; it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the adhesive material of the Anhauser/Liedtke/Engel/Pluim Jr. combination with a synthetic rubber-based adhesive

as taught by Kurokawa in order to provide an adhesive that has no negative effects on human skin.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser in view of Liedtke and Engel, as applied to claims 1, 11 and 18-20 above, and further in view of Kraft et al. (US 4,809,707).

Anhauser/Liedtke/Engel combination is described above; however it does not expressly disclose that the frame- shaped foam plastic layer is a flexible double-adhesive tape.

Kraft teaches a flexible double-adhesive tape (46) surrounding a support element for the purpose of affixing the support element to a patient (column 4, lines 12-14).

Regarding claim 16; it would have been obvious to one having ordinary skill in the art at the time of invention to substitute Anhauser/Liedtke/Engel combination foam plastic layer having adhesive materials on both sides with the double-adhesive tape as taught by Kraft to achieve the predictable result of affixing a support element to a patient.

Response to Arguments

13. Applicant's arguments, see interview summary, mailed on 6/1/2009, with respect to the rejection(s) of all the claim(s) under 35 US 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the Engel reference provided above. The examiner believes the Engel references teaching of providing

adhesive support on both sides of a frame shaped layer makes up for the deficiencies of the previously held rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE
3/17/2010
/A. J. E./

Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736